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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,052	06/20/2003	Aaron Kelly	31132.129	6026
46333	7590	02/13/2006	EXAMINER	
HAYNES AND BOONE, LLP			PHILOGENE, PEDRO	
901 MAIN ST			ART UNIT	
SUITE 3100			PAPER NUMBER	
DALLAS, TX 75202			3733	

DATE MAILED: 02/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/600,052	KELLY ET AL.	
	Examiner	Art Unit	
	Pedro Philogene	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2003.
 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
 4a) Of the above claim(s) 21-25 is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-20 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/18/03</u> . | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20, drawn to a body member, classified in class 623, subclass 23.58.
- II. Claims 21-25, drawn to implantable endoprosthesis, classified in class 623, subclass 23.15.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the body member does not require a shell. The subcombination has separate utility such as a spacer.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

During a telephone conversation with David M. O'Dell on 2/6/06 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-20. Affirmation of this election must be made by applicant in replying to this Office action.

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Claim 21-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 101-103, 106-110, 112-113 of copending Application No. 09/924,298. Although the conflicting claims

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are not identical, they are not patentably distinct from each other because the difference between claims 1-20 of the application and claims 101-103,106-110,112-113 of the copending application lies in the fact that the copending application claims include many more elements and are thus more specific. Thus, the invention of claims 101-103,106-110,112-113 of the copending application is in effect a "species" of the "generic" invention of claims 1-20. It has been held that the generic invention is "anticipated" by the "species" See in re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 1-20 of the application are anticipated by claims 101-103,106-110,112-113 of the copending application, they are not patentably distinct from claims 101-103,106-110,112-113.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4,6-9,17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Weber et al. (6,533,818).

With respect to claim 1, Weber et al disclose a body member (10) for an implantable endoprosthesis, the body member comprising a first component (12)

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formed from a wear resistant first material, and a second component (16) formed from a resilient second material. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

With respect to claims 2, 17, Weber et al disclose a second central component (16) disposed between the first component and a third component (14) also formed from the first material.

With respect to claims 3,4, Weber et al disclose a first material comprising one or more metal alloy (titanium).

With respect to claims 6,7, Weber et al disclose a first material comprising a ceramic comprising alumina or zirconia; ; as set forth in column 5, lines 1-21.

With respect to claims 8, 9, Weber et al disclose first material comprising a wear resistant polymer and the polymer comprises polyethylene; as set forth in column 5, lines 10-15.

With respect to claim 16, Weber et al disclose a polyurethane is a polycarbonate polyurethane; as set forth in column 5, lines 65-67, column 6, lines 1-4.

With respect to claims 18,19, Weber et al disclose a device wherein the third and the first components includes portions including lips protrusion and a flexible engaging member; as best seen in FIGS, 2,4,6.

With respect to claim 20, Weber et al disclose an implantable endoprosthesis comprising wear resistant material selected from the group consisting of ultra-high

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molecular weight polyethylene; as set forth 6, lines 1-4. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5,10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weber et al. (6,533,818).

With respect to claims 5, 10-15, it is noted that Weber et al teach all the limitation except for the alloy being cobalt-chrome alloy; the molecular weight ranging from about 5.0×10^5 grams/mol to about 6.0×10^6 grams/mol; polyethylene having modulus of elasticity ranging from about 0.7 to about 3.0 Gpa; A polyethylene cross-linked to an extent ranging between about 0 to about 50% as measure by a swell ratio; polymer comprising (PEEK) and the second material comprises polymer having durometer ranging from about 75A to about 65D; as claimed by applicant. However, it would have been obvious to one having ordinary skill in the art to use any known or preferred material; since it has been held to be within the general skill of a worker in the art to

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select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416. As to the ranges and percentages as claimed by applicant. It would have been obvious to one having ordinary skill in the art to reach an optimum range, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

5,674,294	10-1997	Bainville et al
5,824,094	10-1998	Serhan et al
6,261,293	07-2001	Nicholson et al


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272 - 4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pedro Philogene
February 07, 2006



PEDRO PHILOGENE
PRIMARY EXAMINER